OCT - 6 2003

K030081 1/2

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (678) 908- 8180
4-Fax: (425) 795- 9341
5-Contact Person: Jay Mansour

6-Date summary prepared: December 28th, 2002

7-Device Trade or Proprietary Name: CSF400™ and CSF600™

8-Device Common or usual name: Central nervous system fluid drainage set

9-Device Classification Name: Central nervous system fluid shunt

10-Substantial Equivalency is claimed against the following device:

- External Ventricular Drainage System from Heyer Schulte
  510k # K820247

11-Description of the Device:

CSF (TM) is a disposable system designed for the drainage of cebrospinal fluid from the brain ventricles to a calibrated collection bag, graduated to provide an approximate volume measurement of the fluid collected.

The radiopaque silicone ventricular catheter has been specially designed to drain the cerebropinal fluid from the ventricles through a series of perforations, and it can be inserted into the ventricular cavity with a 30 cm stainless steel stylet included in the system.

The **CSF (TM)** includes a 400 or 600 ml collection bag (respectively CSF400™ and CSF600™) with a bottom drainage port, a small reservoir of 50 ml for liquid just drained, a 270 mm height scale for system 600 and 200 mm for model 400 which is used for positioning the collection unit, a drip chamber which enables visualization of the CSF flow as the fluid enters the bag and permits an approximate measurement of the drainage flow rate, a one-way valve to prevent reflux of the fluid, a 3 way stopcock and a 20 cc syringe to prime the system before its connection to the catheter.

The system is designed to facilitate ventricular drainage, fluid injection, CSF sampling and intracranial pressure monitoring.

The **CSF (TM)** system is presented individually packed and sterile.

12-Intended use of the device:

CSF (TM) is a disposable system designed for the drainage of cerebrospinal fluid from the brain ventricles to a calibrated collection bag, graduated to provide an approximate volume measurement of the fluid collected, and is indicated for use to relieve elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus).

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SIMILAR** to the predicate device.

FDA file reference number	510k # K820247
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Similar
Electrical safety	Not applicable
Thermal safety	Not Applicable
Radiation safety	Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2003

Inmed LTDA
c/o Mr. Jay Mansour
President
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K030081
Trade/Device Name: CSF400™ and CSF600™
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: July 21, 2003
Received: July 24, 2003

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030081

Device Name: CSF400™ and CSF600™

Indications for Use:

This device is a disposable system designed for the drainage of cerebrospinal fluid from the brain ventricles to a calibrated collection bag, graduated to provide an approximate volume measurement of the fluid collected, and is indicated for use to relieve elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus).

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030081

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)